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510(k) Summary

Pursuant to CFR 807.92, the following 510(k) Summary is provided:

1. (a)	**Submitter's Address:**	George J. Hattub MedicSense, USA 291 Hillside Avenue Somerset, MA 02726
1. (b)	***Manufacturer Address:***	Inolase, Ltd. 13 Giborei Israel St., PO Box 8497 Netanya (New Industrial Area) Israel, 42504
	Mfg. Phone:	972-9-865-6750
	Contact Person:	Raphi Shavit, CEO
	Date:	**Revised- December 26, 2007 (revisions bolded)**
2.	***Device & Classification Name:***	Laser Handpiece Accessory System (Class 2), Product Code GEX, 21 CFR 878.4810 – Tradename of device: Serenity Pro PSF™ System
3.	***Predicate Devices:***	Inolase Serenity PSF™ (Pneumatic Skin Flattening) Systems (K071469), **(K071943)** & **(K062589)**
4.	***Description:***	The Serenity Pro PSF™ System is a device which has the ability to produce a vacuum at a level of 380-680 mbar. Suction can be delivered through its handpiece, which has a sapphire window at its distal end, to be positioned over the skin for laser or IPL treatment. When the PSF system is activated, the negative pressure results in the flattening of the skin of the treatment site. During the time duration of suction, the treatment beam of the laser or IPL is administered through the sapphire window of the handpiece, which is transparent and thermally conductive. The resultant tight mechanical contact produced by the PSF expels blood from the treatment site which enhances the light penetration of the laser or IPL in tissue as well as the removal of its heat from the skin. This can reduce the possibility of post treatment erythema.
5.	***Intended Use:***	The Candela-Inolase Serenity Pro PSF™ (Pneumatic Skin Flattening) System is indicated for the following uses: As an accessory for a compatible legally marketed Laser or Intense Pulse Light System for use in hair removal. Its handpiece produces a negative pressure over the skin surface, just prior to the administration treatment beam through it. Reduction of pain during Laser or Intense Pulse Light System treatment.
6.	***Comparison of Technological Characteristics:***	With respect to technology, the Serenity Pro PSF™ System is substantially equivalent to its predicate device. No changes have been made to the technology. The purpose of the 510(k) was to expand its indications for use for the device.

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510(k) Summary

7. *Performance Data:* The basis for substantial equivalence for this device (K072925) relies upon the clinical data which was submitted in K071469. K071469 was determined to be substantially equivalent by FDA on 8/15/2007.

This data was obtained in a clinical study. The primary objective of the study was to confirm the assumption that the Candela - Inolase Serenity PSF™ (Pneumatic Skin Flattening) System (PSF) reduces laser therapy associated pain. This study involved normal laser treatment parameters which were typically expected to be painful. Evaluation consisted of pain experienced in treated sites with PSF compared with treated sites without PSF. The measurement of immediate post treatment subject pain was recorded utilizing a modified McGill Pain questionnaire, which is commonly used in pain evaluation.

A secondary objective of this clinical study was to confirm that the use of PSF decreased the erythema associated with current laser therapy. The clinical investigators rated erythema immediately and 20 minutes post treatment for standard laser treatment laser vs. laser with PSF.

The results of the clinical data indicated that the Candela - Inolase Serenity PSF™ (Pneumatic Skin Flattening) System (PSF) significantly reduces the pain associated with laser hair removal and that the side effect of erythema was lessened with PSF vs. without PSF standard laser treatment.

In terms of fundamental technology and intended use, the device (K071469), which was utilized in the clinical study, is essentially the same as the device (K072925), which is subject of this 510(k) submission. Therefore, this clinical study is relevant to this 510(k) submission and, Candela - Inolase has concluded that no new safety or efficacy issues have been raised.

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Indications for Use

510(k) Number (if known):

Device Name: Candela-Inolase Serenity Pro PSF™ (Pneumatic Skin Flattening) System

Indications For Use:

The Candela-Inolase Serenity Pro PSF™ (Pneumatic Skin Flattening) System is indicated for the following uses:

As an accessory for a compatible legally marketed Laser or Intense Pulse Light System for use in hair removal. Its handpiece produces a negative pressure over the skin surface, just prior to the administration treatment beam through it.

Reduction of pain during Laser or Intense Pulse Light System treatment.

Prescription Use ___x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 10 2008

Inolase, Ltd.
% MedicSense, USA
Mr. George J. Hattub, RAC & CQE
Senior Staff Consultant
291 Hillside Avenue
Somerset, Massachusetts 02726

Re: K072925
Trade/Device Name: Candela-Inolase Serenity Pro PSF™ (Pneumatic Skin Flattening) System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: October 9, 2007
Received: October 24, 2007

Dear Mr. Hattub:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known):

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Reduction of pain during Laser or Intense Pulse Light System treatment.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072925